



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Marie-Cecile van de Lavoie et al.

) Group Art Unit: 1636

Serial No. 10/067,148

) Examiner: Sumesh Kaushal

Filed: February 1, 2002

For: CHIMERIC BIRD FROM
EMBRYONIC STEM CELLS

AFFIDAVIT OF ROBERT J. ETCHES PURSUANT TO 37 C.F.R. § 1.132

MAIL STOP

Commissioner of Patents

Washington, D.C. 20231

Sir:

1. I am one of the inventors of United States Patent application Serial No. 10/067,148.
2. I received a B.Sc. (Agr) specializing in poultry breeding and genetics from the University of British Columbia in 1970, a MSc in poultry genetics and physiology from McGill University in 1972, a PhD in physiology and biochemistry in endocrine control of the ovulatory cycle of the hen from the University of Reading in 1975 and a DSc from the University of Reading in 1985 in recognition of contributions to the field of avian reproduction.
3. I am Vice President of Research of Origen Therapeutics, Inc. I have 29 years of experience in avian genetics and 14 years of experience in culture of chicken embryonic stem cells.
4. I am a co-author of a paper by Pain et al. Development 122, 2339-2348 (1996) cited by the Examiner in the most recent office action.

5. None of the embryonic stem cell cultures disclosed in the 1996 Pain et al. paper contained a stably integrated transgene incorporated into a genome of the embryonic stem cells or any progeny thereof.

6. Although the work described in the Pain et al. paper involved long-term cultures of chicken embryonic stem cells, none of this work resulted in the successful generation of chimeras from embryonic stem cells or their progeny held in culture for longer than 19 days. This fact is reflected in the legend to Figure 8 of the Pain et al. paper where the authors recited the longest culture period from which chimeric birds have been generated.

7. In contrast, the above-cited patent application describes the development of chimeric chickens from an embryonic stem cell culture that is maintained for more than 60 days. The significance of this time period is that it allows the time necessary to transfect, select, and isolate ES cell lines carrying a stably integrated transgene into the genome of the embryonic stem cells held in culture.

8. Also, when these transformed embryonic stem cells are inserted into a recipient embryo, the expression of the stably integrated transgene may be detected in several tissue types of the resulting chimeric chicken.

9. Given that the longest period of time in which cells had been maintained in culture and demonstrated to have the capability to contribute to the somatic tissue of a chimeric chicken was 19 days according to the Pain et al. paper, it would not have been expected that the chicken ES cells could be maintained in culture for a period of time long enough to be transformed such that a transgene was stably integrated into the genome of the cells while maintaining the ability of the cells to colonize somatic tissues and differentiate into specialized cell types when these transformed chicken embryonic stem cells were injected into a recipient

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embryo. The pending application describes the first example known to me of a live hatched chimeric chicken carrying embryonic stem cell progeny which express a transgene that has been stably integrated into the genome of the embryonic stem cells used to create the chimera and where expression of that transgene is detected in the somatic tissue of the resulting chicken.

10. I, the undersigned inventor, being hereby warned that willful false statements made herein are punishable by fine or imprisonment or both under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon, do hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true.

Date: April 28, 2004

By: 

Robert J. Etches, Ph.D.